



**CTMS Adverse Events Reporting SIG Teleconference  
Meeting Minutes**

<b>Meeting Date</b>	Wednesday, September 3, 2004 3:00 – 4:00 PM EDT																														
<b>Attendees:</b>	<p><b>Working group coordinator:</b> Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton)</p> <p><b>Participants:</b></p> <table><tr><th>Name</th><th>Email</th><th>Center</th></tr><tr><td>Joyce Niland (SIG lead)</td><td>jniland@coh.org</td><td>City of Hope</td></tr><tr><td>Diane Paul</td><td>funnylady93@earthlink.net</td><td>CARRA</td></tr><tr><td>Hemant Shah</td><td>hshah@coh.org</td><td>City of Hope</td></tr><tr><td>Erin Iturriaga</td><td>iturriae@mail.nih.gov</td><td>DCP</td></tr><tr><td>John Speakman</td><td>speakman@biost.mskcc.org</td><td>Sloan-Kettering</td></tr><tr><td>Andrea Hwang</td><td>ychwang@uci.edu</td><td>UC Irvine</td></tr><tr><td>Bob Morrell</td><td>bmorrell@wfubmc.edu</td><td>Wake Forest</td></tr><tr><td>Rhoda Arzoomanian</td><td>rza@medicine.wisc.edu</td><td>Wisconsin</td></tr><tr><td>Amy Cox</td><td>acox@coh.org</td><td>City of Hope</td></tr></table>	Name	Email	Center	Joyce Niland (SIG lead)	jniland@coh.org	City of Hope	Diane Paul	funnylady93@earthlink.net	CARRA	Hemant Shah	hshah@coh.org	City of Hope	Erin Iturriaga	iturriae@mail.nih.gov	DCP	John Speakman	speakman@biost.mskcc.org	Sloan-Kettering	Andrea Hwang	ychwang@uci.edu	UC Irvine	Bob Morrell	bmorrell@wfubmc.edu	Wake Forest	Rhoda Arzoomanian	rza@medicine.wisc.edu	Wisconsin	Amy Cox	acox@coh.org	City of Hope
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<b>Agenda</b>	<p>I. Review of Minutes: August 11, 2004</p> <p>II. Updated Proposed AE System High Level Diagram Review Amy Cox – COH</p> <p>III. CaBIG AE, CTMS-CDUS Survey Summary Review Dr. Niland and Amy Cox – COH</p> <p>IV. CaBIG Clinical Trial Management Systems Quarterly In-Person Meeting Location: City of Hope National Medical Center Duarte, CA Dates: November 16 – 17, 2004</p> <p>V. Future Plans</p> <p>VI. Next Meeting: September 17, 2004</p>																														

<p><b>General discussion points raised by participants:</b></p>	<ul style="list-style-type: none"> <li>• Amy Cox presented an updated flow diagram for identifying and reporting adverse events based on feedback from previous teleconference. Information flow processes from the perspective of four actors: cancer center, cancer center system(s), caBIG adverse events system and participant were described. The actor “Patient” was renamed to Participant and was meant to denote a research subject. Hemant Shah suggested the use of the term “Affected individual” based on the ICSR ballot of HL7, which could imply a study participant, a relative of a patient or a fetus.</li> <li>• Potential problems created as a result of differences in the codes or fields used to represent or store data by legacy systems and caBIG systems were discussed. A mapping or translation table, which would synchronize or translate the different nomenclatures was proposed.</li> <li>• The need for an executive committee to review adverse events (content, timing, etc.) before posting to a website was raised. This could be the function of an external advisory agency.</li> <li>• The results of the AE / CTMS – CDUS SIG Survey that was sent to 30-odd centers was presented by Joyce Niland and Rhoda Arzoomanian. The survey polled centers for types of AE data collection systems, existing systems functionality, legacy AE reporting systems/databases (which included vendor and home-grown systems), type of CTMS and CDUS data capture and reporting capabilities and issues/barriers with CTMS and/or CDUS report systems.</li> <li>• The different practices used by cancer centers for grading toxicities as expected or unexpected was discussed.</li> </ul>
<p><b>Action items:</b></p>	<ul style="list-style-type: none"> <li>• Distribute version 3 of the AE / CTMS – CDUS SIG survey</li> <li>• Review optimal idealized workflow for harmonized unified AE reporting module</li> <li>• Incorporate electronic changes to Activity Diagram from CTEP and complete the CTEP workflow</li> <li>• Obtain rule tables from CTEP for triggering AE reporting from Ann Setser</li> <li>• Present flowchart of DCP AE information flow after appropriate reviews</li> </ul>